HHS SBIR RFA-HL-14-012

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Description:
Purpose

A major objective of the Small Business Innovation Research (SBIR) Program is to facilitate the commercialization of technologies developed by small business concerns (SBCs). The development of biomedical products is often impeded by a significant funding gap between the end of the SBIR Phase II award and the commercialization stage. This gap is increased by the barriers associated with technologies under development for small commercial markets, such as rare diseases or young pediatric populations. This Funding Opportunity Announcement (FOA) solicits SBIR grant applications from SBCs to support later stage research and development (referred to as Phase IIB) for promising projects that were previously funded by SBIR Phase II awards that address rare diseases or young pediatric populations (aged 0-12 years and defined in Section IV, part 6), and will require eventual Federal regulatory approval/clearance. The goal of this FOA and the resulting Phase IIB awards is to assist applicants in pursuing the next appropriate milestone(s) necessary to continue development with private funding after NHLBI support ends by promoting partnerships between SBIR Phase II awardees and third-party investors and/or strategic partners.

- This FOA will give competitive preference and funding priority to applicants that secure independent third-party investor funds that equal or exceed one-third of the requested NHLBI funds (total costs).
- This FOA is specifically intended to benefit patients by accelerating the commercialization of

novel products and technologies that address a rare disease or young pediatric populations.
- Proposed projects MUST be relevant to the NHLBI mission (see B. Scientific/Technical Scope) and require ultimate approval/clearance by a Federal regulatory agency.

Background

Since its inception in 1982, the NIH SBIR program has provided the small business community with seed funding to support the development of a broad array of commercial products to detect, diagnose, treat, and prevent disease. It provides an important mechanism for bringing new interventions to patients and clinicians. The SBIR program is structured in three phases. The objective in Phase I is to establish the technical merit and feasibility of a proposed research and development (R&D) effort, while in Phase II it is to continue the R&D effort for successful Phase I projects. The expectation is that in Phase III, an SBC will be able to complete commercialization with non-NIH funds. However, many projects initiated with SBIR funding require considerable financing beyond the SBIR Phase II award to complete the necessary validation studies required to arrive at Phase III. In particular, the development of therapeutics, medical devices, and combined technologies often requires a number of years and substantial capital investments because of the costs associated with conducting clinical trials and/or other steps mandated by the federal regulatory approval process. Companies developing products that have small potential revenue streams or target small patient populations face additional barriers to market entry that make them less attractive at pre-clinical or early clinical stages of development to investors and strategic partners. In addition, many of these technologies require complex clinical trial designs because of small and geographically diverse patient populations. Thus, despite the extensive R&D efforts during Phase II projects in these areas, the results are often insufficient to attract private investments needed for the eventual commercialization of a product.

This FOA is designed to address this funding gap for technologies primarily focused on rare diseases or young pediatric populations. A major goal of this FOA is to provide a platform to incentivize partnerships between SBIR awardees and a broad range of potential third-party investors. It is anticipated that funding by third-party investors will be predicated on significant due diligence, thus encouraging awardees to formulate credible business plans for product commercialization. In addition, it is expected that third-party investors will maintain an active role in supporting the awardee during the product development phase and during pursuit of follow-on funding for the SBIR Phase III commercialization stage.

The NHLBI has published a separate FOA, the Bridge Award (RFA-HL-13-016), to address a similar critical gap for projects that do not meet the responsiveness criteria of the Small Market Award.

Specific Objectives for SBIR Phase IIB Small Market Award Applications

A. Independent Third-Party Investor Funds

This FOA specifically encourages business relationships between applicant SBCs and third-party investors/strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR funding. In particular, applicants are expected to leverage their previous SBIR support, as well as the opportunity to compete for additional NHLBI funding under this FOA, to attract and negotiate third-party financing needed to advance a product or technology toward commercialization. The applicant's ability to secure independent third-party investor funds that equal or exceed one-third of the total amount of NHLBI funds being requested over the entire project period will help validate the commercial potential that is essential for the SBIR projects solicited under this FOA. This potential will be strongly considered in review (refer to Section V. Application Review Information) and making funding decisions. It is anticipated that many of the partnerships between applicant SBCs and third-party investors will involve a considerable level of project due diligence by the private sector, thereby increasing the likelihood of commercial success for the funded projects. In light of these goals, the NHLBI strongly encourages applicants to establish business relationships with investors and/or strategic partners that have appropriate prior experience in commercializing emerging biomedical technologies addressing rare diseases or young pediatric populations.

B. Scientific/Technical Scope

The technical and commercial objectives described in the SBIR Phase IIB Small Market Award application MUST represent an extension of the development efforts that were pursued in a previously funded SBIR Phase II award. It is essential that significant progress was accomplished during the current/preceding SBIR Phase II project and also that the proposed product/technology has commercial potential. Applicants should also be able to demonstrate that the proposed product/technology has a clear advantage over existing and/or competing products/technologies and should clearly define an appropriate path toward ultimate product commercialization.

This FOA is specifically designed to provide additional support for products/technologies that require ultimate approval by a Federal regulatory agency.

Projects previously funded by another NIH Institute/Center or another Federal agency are eligible to apply under this FOA, provided proposed projects are relevant to the NHLBI mission. Applicants should contact the NHLBI Scientific/Research Contact **listed under Section VII. to discuss whether their proposed project meets this criterion.**

The NHLBI supports development of technologies to detect, prevent, or treat cardiovascular, lung, blood and sleep disorders. It also supports research on the clinical use of blood and all aspects of the management and safety of blood resources. The NHLBI SBIR/STTR program fosters basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. The NHLBI program priority areas for technology development research under this FOA include, but are not limited to:

- Blood Diseases and Resources areas: *in vitro* diagnostic devices and therapeutic biologics, devices and drugs for rare diseases, and diseases affecting young children and neonates, including, but not limited to, coagulation and other laboratory based assays; transfusion/infusion and non-transfusion/non-infusion treatments for bleeding complications in acquired and inherited bleeding disorders; point of care diagnostics for Sickle Cell Disease and other hemoglobinopathies to facilitate testing in low resource settings to provide earlier diagnosis and access to medical interventions; devices that facilitate transfusion of small volumes of blood components; and long-term, indwelling catheters for transfusion, blood sample collection or medication administration that provide very low thrombosis/infection risk.
- Cardiovascular Diseases areas: diagnostics, therapeutics (including cell and gene therapies), or instruments for treating congenital or acquired heart disease in young pediatric populations, including heart pumps and valves, atrial septal defect closure devices, surgical tools, and devices for cardiac catheterization; diagnostics and therapies for rare arrhythmias (such as LQTS-1, -2, and -3, Brugada’s, and Timothy’s syndromes) and lipid disorders (such as lecithin-cholesterol acyltransferase or lipoprotein deficiencies or genetic diseases such as Pompe disease); technologies, instruments, and therapeutics for heart (and lung) transplantation, including devices for perfusion of donor organs and technologies for less invasive tissue biopsies and detection of organ rejection.
- Lung Diseases areas: diagnostics and therapeutics for rare lung diseases and those affecting young pediatric populations, including, but not limited to respiratory distress syndrome, cystic fibrosis, adult and pediatric pulmonary arterial hypertension, adult and childhood interstitial lung diseases, Lymphangioleiomyomatosis, and sarcoidosis. Examples include, but are not limited to, non-invasive monitoring of cardiopulmonary function for neonates and young children, portable imaging systems compatible with Intensive Care Unit environments, therapies to prevent bronchopulmonary dysplasia, improved aerosol delivery devices for young children, portable home diagnostic and treatment devices for sleep disordered breathing in young pediatric populations.

The following provides examples of appropriate development activities for this FOA. Responsive applications are not limited to the following areas:

- For projects pertaining to the development of therapeutics, applicants are expected to

propose activities that will lead to the successful filing of an Investigational New Drug (IND) application or clinical studies to support the filing of a New Drug Application (NDA) and/or Biological License Application (BLA).
- For projects pertaining to imaging technologies, interventional devices, and *in vivo* diagnostics, applicants are expected to propose activities that will lead to the successful filing of a Pre-Market Notification, 510(k) application, Premarket Approval (PMA) application, or an Investigational Device Exemption (IDE) application.
- For projects pertaining to *ex vivo* or *in vitro* diagnostics, prognostics, and screening tests, applicants are expected to propose activities that will lead to the successful filing of a 510(k) application, Premarket Approval (PMA) application, an Investigational New Drug (IND) application, and/or Investigational Device Exemption (IDE) application, as needed for the specific technology/system/assay.

Activities to be pursued under this FOA should address any relevant requirements for clinical validation and regulatory approval, as necessary and required for commercialization of the technology. Specific activities to be pursued will vary among applications.

C. Plan for Full Commercialization

The goal of the SBIR Phase IIB Small Market Award is to advance SBIR Phase II projects toward ultimate commercialization. All applicants are expected to describe a realistic plan (extending beyond the SBIR Phase IIB Small Market Award project period) that outlines how and when full commercialization can be accomplished. The long-term commercialization strategy should be presented as part of the Commercialization Plan. The full commercialization plan for the product/technology should extend beyond the period of SBIR funding.

Applicants are encouraged to leverage other available Federal resources where appropriate, including existing FDA incentives to increase and accelerate small market product development, such as Orphan Drug designation, Humanitarian Device Exemption, and the Pediatric Exclusivity Provision. In addition, applicants may be eligible to participate in the NIH Therapeutics for Rare and Neglected Diseases (TRND) program (http://www.ncats.nih.gov/research/rare-diseases/trnd/trnd.html) and Bridging Interventional Development Gaps (BrIDGs) program (http://www.ncats.nih.gov/about/faq/bridgs/bridgs-faq.html). To enter either TRND or BrIDGs, the applicant needs to apply through a separate peer-reviewed open solicitation. Projects selected for either of these programs will get in-kind funding and resources to support drug development projects aiming to bring novel therapies to treat rare diseases.